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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,396	07/27/2001	Gregory M. Fahy	CENTMED.020A	7764

7590 06/16/2004  
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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/916,396	<b>Applicant(s)</b> FAHY, GREGORY M.	
	<b>Examiner</b> Sandra Saucier	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,13,15,19-22 and 25-37 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,19 and 27-29 is/are rejected.
- 7) ☒ Claim(s) 3,4,10,13,15,20-22,25,26 and 30-36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

DETAILED ACTION

Claims 1-4, 6-10, 13, 15, 19-22, 25-37 are pending. Claims 1-4, 6, 7, 10, 13, 15, 19-22, 25-36 are considered on the merits. Claims 8, 9 and 37 are withdrawn from consideration as being drawn to a non-elected invention.

***Election/Restrictions***

Newly submitted claim 37 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original claims are directed to a composition comprising mannitol and lactose, while new claim 37 is directed to a distinct composition comprising trehalose and lactose.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 37 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112  
NEW MATTER

Claim 7 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Insertion of "sucrose" in the claimed composition of claim 7 appears to be new matter. No mention of sucrose being included in the composition appears in the narrative portion of the specification, in the original claims or in any of the exemplified species.

The only mention of sucrose is on page 6, paragraph 22, where it is said that sucrose was considered to be undesirable due to its high viscosity and reported nephrotoxicity. This is not a teaching of the inclusion of sucrose, but rather reasons why the popular impermeant was NOT USED IN THE PRESENT COMPOSITIONS. Further, sucrose is not a polymer as is required by the preamble of claim 7. Or are applicants attempting to incorporate new matter by claiming polymers of sucrose?

One is not free to expand the scope of the disclosure or to introduce new concepts during prosecution.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification.

#### INDEFINITE

Claims 27-29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that X1000 is described in the legend of Table 2. It is apparent from the legend that this is a trade name of a commercial product.

If a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

See MPEP 2173.05(u) Trademarks or Trade Names in a Claim.

#### Claim Rejections - 35 USC § 102

Claims 1, 2, 7, 19 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 1-106826 [L].

The claims are directed to a composition for the introduction and washout of vitrifiable concentration of cryoprotectants comprising: mannitol, lactose.

JP 1-106826 disclose a solution used for the preservation of red cells comprising mannitol, lactose with other sugars and sugar alcohols, see abstract.

#### Response to Arguments

Applicant's arguments filed 4/16/04 have been fully considered but they are not persuasive.

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Applicant argues that the preamble of claim 1 cannot be ignored as it is in Jepson format. This is true and the preamble has been given weight as urged by applicant. The preamble states that this is a carrier solution for the introduction and washout of cryoprotectants. If the solution of the prior art is capable of performing the intended use as recited in the preamble, then it meets the claim. The solution of JP 1-106826 is capable of being used to introduce and washout cryoprotectants from cells/organs because it is a solution used in a biological field and is thus, suitable for use with cells/tissue/organs.

Applicant argues that the reference fails to disclose the combination of mannitol and lactose. Please read the abstract again where it is stated that the inventive solution is made by combining (I) with base liquid of ACD... and SAG solution containing mannitol...sucrose and lactose. The abstract certainly states that these three carbohydrates are in the solution together.

Applicant argues that the solution of the reference does not have the instantly disclosed utility. Please note the claims being examined are composition claims not method of use claims. Use is not given much patentable weight in composition claims if the prior art composition is capable of being put to the intended use. The examiner's position is that the prior art solution is capable of being used as a carrier/washout solution because it is disclosed in the prior art as being used with red cells which are a biological entity.

#### Claim Rejections - 35 USC§103

Applicant states that US'137 does not disclose the use of mannitol and lactose in the same solution nor even in separate solutions for the same purpose.

Upon careful rereading of the reference, it is acknowledged that the solutions containing lactose and mannitol are distinct solutions used for distinct purposes and the rejections over US'137 are withdrawn.

#### ***Allowable Subject Matter***

4 Claims 3, 4, 6, 10, 13, 15, 20-22, 25, 26, 30-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Method claims 8 and 9 may be rejoined upon request as long as they are dependent on an allowable composition claim and do not introduce new matter or other issues under USC§112.

Please cancel claim 37 in your response to facilitate allowance.

**Conclusion**

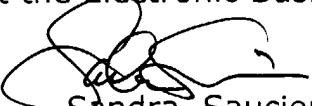
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sandra Saucier  
Primary Examiner  
Au 1651